Wiener lab.
Especialidades para Laboratorios Clínicos
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FEB 1 2 2003

Section 6 – Summary

510(k) Summary
"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92"

"The assigned 510(k) number is: K024116 **"**

Introduction

According to the requirements of 21 CFR 862.1110, the following information provides sufficient details to understand the basis of a determination of substantial equivalence.

6-1 Submitter Name, Address, Contact

Wiener Laboratorios S.A.I.C.
Riobamba 2944
2000 – Rosario – Argentina
Tel: 54 341 4329191
Fax: 54 341 4851986
Contact person: Viviana Cétola
Date Prepared: September 15, 2002

6-2 Device Name

Proprietary name: Wiener lab. BILIRRUBINA DIRECTA AA

Common name: Bilirubin (total or direct) test system

Classification name: Diazo colorimetry, Bilirubin

Device Class II

6-3 Predicate Device

We claim substantial equivalence to the currently marketed DMA Direct Bilirubin Plus test system (Cat. Nº1225).

6-4 Device Description

Direct bilirubin is measured using a stable dichloro-phenyldiazonium salt (DPD) to form a red azocompound in an acid solution, with maximal O.D. at 546 nm.

The amount of direct bilirubin is determined by measuring the absorbance of this pigment.

6-5 Intended Use

The WIENER LAB. BILIRRUBINA DIRECTA AA test system is a quantitative in vitro diagnostic device intended to be used in the determination of direct bilirubin in human sera and heparinized plasmas on both manual and automated systems. Measurements of the levels of bilirubin, and organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder block.

6-6 Equivalencies and Differences

The WIENER LAB. BILIRRUBINA DIRECTA AA test system is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed DMA Direct Bilirubin Plus test system.

The following table illustrates the similarities and differences between the WIENER LAB. Bilirrubina Directa AA test system and the currently marketed DMA Direct Bilirubin Plus test system.

	DMA Test System	**WIENER LAB. Test System**
Intended Use	Quantitative determination of direct bilirubin in human serum.	Quantitative determination of direct bilirubin in human serum and heparinized plasma.

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	DMA Test System	WIENER LAB. Test System
Test Principle	Conjugated billirubin reacts with diazotized sulfanilic acid to produce an acid azobilirubin, the absorbance of which is proportional to the concentration of direct bilirubin in the sample can be measured at 550 nm.	Direct bilirubin is measured using a stable dichlorophenyldiazonium salt (DPD) to form a red azocompound in an acid solution, with maximal O.D. at 546 nm. The amount of direct bilirubin is determined by measuring the absorbance of this pigment.
Reagents	Bilirubin Reagent: hydrochloric acid and sulfanilic acid. Sodium Nitrite Reagent: sodium nitrite.	R1: sulfamic acid. R2: dichlorophenyl-diazonium salt. Reagent for sample blank: sulfamic acid.
Sample	Human serum.	Human serum and heparinized plasma.
Wavelength of Reading	550 nm	Spectrophotometer: 546 nm Photocolorimeter with green filter: 520 – 550 nm
Linearity	12 mg/dl	14 mg/dl
Expected values	0.0 – 0.2 mg/dl	

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	DMA Test System	WIENER LAB. Test System
Within-run precision	Normal Level Serum: CV = <1% High Level Serum: CV = 2.8%	Normal Level Serum: CV = 4.03% High Level Serum: CV = 1.33%
Total-run precision.	Normal Serum Control: CV = 8.8%% Abnormal Serum Control: CV = 4.4%	Normal Serum Control: CV = 5.09% Abnormal Serum Control: CV = 2.00%

6-7 Conclusion Above mentioned data show substantial equivalency to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 12 2003

Dr, Viviana Cetola
QC/QA Manager
Weiner Laboratorios S.A.I.C.
Riobamba 2944
Rosario, Santa Fe
Argentina 2000

Re: k024116
Trade/Device Name: Weiner Labs Bilirrubina directa AA
Regulation Number: 21 CFR 862.1110
Regulation Name: Bilirubin (total or direct) test system
Regulatory Class: Class II
Product Code: CIG
Dated: November 26, 2002
Received: December 13, 2002

Dear Dr. Cetola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K024116

Device Name: Wiener lab.
Bilirrubina directa AA

Indications For Use:

The "Wiener lab. Bilirrubina directa AA" test system is a quantitative in vitro diagnostic device intended to be used in the determination of direct bilirubin in human sera and heparinized plasmas on both manual and automated systems. Measurements of the levels of bilirubin, and organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder block.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K024116